

37



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,639	01/09/2002	Patricia Sarcabal	CHEP:004US	6528
7590	07/29/2005			
Mark B. Wilson Fulbright & Jaworski L.L.P. Suite 2400 600 Congress Avenue Austin, TX 78701			EXAMINER FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 07/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/043,639

Applicant(s)

SARCABAL ET AL.

Examiner

Christian L. Fronda

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-67 and 82-84 is/are pending in the application.
- 4a) Of the above claim(s) 33-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-67 and 82-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 05/16/2003 05/16/2002
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1652

DETAILED ACTION

Election/Restriction

1. Applicants' election without traverse of Group II (claims 50-67 and 82-84) is acknowledged. Claims 33-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The restriction requirement is still deemed proper and is therefore made FINAL.
2. Claims 50-67 and 82-84 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
4. Claim 64 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.
The claim, as written, do not sufficiently distinguish over cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "an isolated host cell". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out

Art Unit: 1652

his invention.

6. Claims 50, 51, 57, 61-64, and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims directed toward a highly variant genus of polynucleotides that encode any glycerol dehydratase and a highly variant genus of polynucleotides that encode any glycerol dehydratase further comprising any glycerol-3-phosphate dehydrogenase and glycerol-3-phosphatase. Each genus encompasses polynucleotides having widely differing biological activities, nucleotide sequences, structures, and physiochemical properties. Each genus is highly variable because a significant number of structural differences between genus members exists.

The specification discloses the recombinant polynucleotide consisting of SEQ ID NO: 1 and SEQ ID NO: 2, the recombinant polynucleotide consisting of SEQ ID NO: 5 and SEQ ID NO: 3, the recombinant polynucleotide encoding the amino acid sequences of SEQ ID NO: 6 and SEQ ID NO: 7, and the recombinant polynucleotide encoding the amino acid sequence of SEQ ID NO: 4. However, the specification does not provide a written description of any other members of each claimed genus. The specification fails to provide information regarding the nucleotide sequence and structure that is common to all members of each claimed genus.

Thus in view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed genus of polynucleotides that encode any glycerol dehydratase and the claimed genus of polynucleotides that encode any glycerol dehydratase further comprising any glycerol-3-phosphate dehydrogenase and glycerol-3-phosphatase.

7. Claims 52-67 and 82-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the recombinant polynucleotide of consisting of SEQ ID NO: 1, SEQ ID NO: 2, and SEQ ID NO: 4; the recombinant polynucleotide of SEQ ID NO: 5; the recombinant polynucleotide consisting of SEQ ID NO: 5 and SEQ ID NO: 3; and the recombinant polynucleotide encoding the polypeptide consisting of SEQ ID NO: 6 and SEQ ID NO: 7; does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Art Unit: 1652

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass polynucleotides encoding glycerol dehydratases at least 50% nucleotide identity to SEQ ID NO: 1, 50% nucleotide identity to SEQ ID NO: 2, 90% nucleotide identity to SEQ ID NO: 4, 90% identity to SEQ ID NO: 5, 80% nucleotide identity to SEQ ID NO: 3, and polynucleotides encoding 50% amino acid identity to SEQ ID NO: 6 and/or SEQ ID NO: 7 and 90% amino acid identity to SEQ ID NO: 8. The specification provides guidance and examples for making the recombinant polynucleotide consisting of SEQ ID NO: 1 and SEQ ID NO: 2, the recombinant polynucleotide consisting of SEQ ID NO: 5 and SEQ ID NO: 3, the recombinant polynucleotide encoding the amino acid sequences of SEQ ID NO: 6 and SEQ ID NO: 7, and the recombinant polynucleotide encoding the amino acid sequence of SEQ ID NO: 4.

While molecular biological techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the specific nucleotides or amino acids to change (i.e. delete, insert, substitute, and combinations thereof) in SEQ ID NOs: 1-8 to make the recited polynucleotides is lacking. The specification nor the general knowledge of those skilled in the art do not provide guidance, prediction, and working examples showing specific nucleotides or amino acids that can be changed without affecting the biological function of the polynucleotide. Thus, an undue amount of experimentation must be performed to determine these nucleotides or amino acids to change. Searching and screening for the claimed invention is not guidance for making the invention. Furthermore, searching and screening for the claimed invention is outside the realm of routine experimentation.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotides or amino acids in SEQ ID Nos: 1-8 to change without affecting biological activity. Without such a guidance, the amount of experimentation left to those skilled in the art to make the invention of claims 52-67 and 82-84 is undue.

8. Claim 65 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the recited *E.coli* filed at the NCCM under the access No. I-2243 is required to practice the claimed invention. As such the it must be readily available or obtainable

Art Unit: 1652

by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC § 112, first paragraph, may be satisfied by a deposit of the *E.coli E.coli* filed at the NCCM under the access No. I-2243.

The process disclosed in the specification to make the recited *E.coli* strain does not appear to be repeatable. The specification discloses a polynucleotides and plasmid vectors used in its construction. However, the nucleotide sequences of the plasmid vectors are not fully disclosed, nor have all the nucleotide sequences required for their construction been shown to be biblically known and freely available. The specification does not disclose a repeatable process to obtain the plasmid vectors and it is not apparent if the nucleotide sequences of the polynucleotides and novel vectors are readily available to the public. It is not apparent if the recited *E.coli* strain or source materials to make the said *E.coli* strain are both known and readily available to the public.

Applicants' referral to deposit of the recited *E.coli* strain in the specification is noted but is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met.

While Applicants have deposited the recited *E.coli* filed at the NCCM under the access No. I-2243, there is no indication in the specification as to public availability.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, the applicant may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

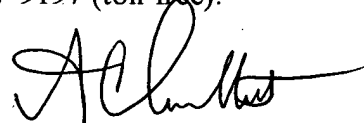
- (1) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;
- (3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (4) the deposit will be replaced if it should ever become inviable.

Art Unit: 1652

Conclusion

9. No claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.
11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600